

DOCOSANOL- docosanol cream
Alembic Pharmaceuticals Inc.

Docosanol Cream, 10%

Active ingredient

Docosanol 10%

Purpose

Cold sore/fever blister treatment

Uses

- treats cold sores/fever blisters on the face or lips
- shortens healing time and duration of symptoms:
 - tingling, pain, burning, and/or itching

Warnings

Allergy Alert

This product may cause a severe allergic reaction. Symptoms may include:

- hives
- facial swelling
- wheezing/difficulty breathing
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

For external use only

Do not use

- if you are allergic to any ingredient in this product

When using this product

- apply only to the affected areas
- do not use in or near the eyes
- avoid applying directly inside your mouth
- do not share this product with anyone. This may spread the infection.

Stop use and ask a doctor if

- your cold sore gets worse or the cold sore is not healed within 10 days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children 12 years or over:**
 - wash hands before and after applying cream
 - apply to affected area on face or lips at the first sign of cold sore/fever blister (tingle)
 - early treatment ensures the best results
 - rub in gently but completely
 - use 5 times a day until healed
- **children under 12 years:**ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)
- do not freeze

Inactive ingredients

benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate, sucrose stearate

Questions or comments?

Call **1-866-210-9797** Monday-Friday 9AM-6PM EST

Principal Display Panel

Tube Pack

NDC 62332-682-01

Docosanol Cream, 10%

Compare to the active ingredient in Abreva®**

Cold Sore/Fever Blister Treatment

Non-prescription Medicine to Shorten Healing Time*

Cold Sore Treatment

For Topical Use Only

NET WT 2g (0.07 oz)

**This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Abreva®.

*Contains the only non-prescription cold sore medicine approved by the FDA to shorten healing time and duration of symptoms.

RETAIN THIS INSERT FOR FULL PRODUCT USES, DIRECTIONS AND WARNINGS

Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

Made in India.

Retain this insert for full product uses, directions and warnings.

<p>Drug Facts</p> <p>Active ingredient Purpose Docosanol 10% Cold sore/fever blister treatment</p> <p>Uses</p> <ul style="list-style-type: none"> treats cold sores/fever blisters on the face or lips shortens healing time and duration of symptoms: <ul style="list-style-type: none"> tingling, pain, burning, and/or itching <p>Warnings</p> <p>Allergy alert This product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> hives wheezing/difficulty breathing shock facial swelling rash <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>For external use only</p> <p>Do not use if you are allergic to any ingredient in this product</p> <p>When using this product</p> <ul style="list-style-type: none"> apply only to affected areas do not use in or near the eyes avoid applying directly inside your mouth do not share this product with anyone. This may spread infection. 	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> your cold sore gets worse or the cold sore is not healed within 10 days <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 12 years or over: <ul style="list-style-type: none"> wash hands before and after applying cream apply to affected area on face or lips at the first sign of cold sore/fever blister (tingle) early treatment ensures the best results rub in gently but completely use 5 times a day until healed children under 12 years: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> store at 20° to 25°C (68° to 77°F) do not freeze <p>Inactive ingredients benzyl alcohol, light mineral oil, propylene glycol, purified water, sucrose distearate, sucrose stearate</p> <p>Questions or comments? Call 1-866-210-9797 Monday-Friday 9AM-6PM EST</p>
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Bedminster, NJ 07921, USA Mfg. License No.: G/25/2216

N 3 6 2 3 3 2 1 6 8 2 0 1 0

UVZ
30 x 11mm

5/2022
XXXXXXXXXX
Sap Code

Compare to the active ingredient in Abreva^{®**} NDC 62332-682-01

Docosanol Cream, 10%

Cold Sore/Fever Blister Treatment

Non-prescription Medicine to Shorten Healing Time*

- Cold Sore Treatment
- For Topical Use Only

NET WT
2 g
(0.07 oz)

Alembic

Open From Here

Batch Coding
(For Reference Only)
LOT: 1234567890
EXP.: MMM YYYY

Pump Pack

NDC 62332-682-03

Docosanol Cream, 10%

Compare to the active ingredient in Abreva[®]**

Cold Sore/Fever Blister Treatment

Non-prescription Medicine to Shorten Healing Time*

Cold Sore Treatment

For Topical Use Only

NET WT 2g (0.07 oz)

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Manufactured for:

Alembic Pharmaceuticals, Inc.

Bedminster, NJ 07921, USA

Made in India.

Retain this insert for full product uses, directions and warnings.



Press Pump completely about 6 to 8 times to get first dose.



Drug Facts

Active ingredient Purpose
 Docosanol 10% Cold sore/fever blister treatment

Uses

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Drug Facts (continued)

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Manufactured for: **Alembic Pharmaceuticals, Inc.**
 Bedminster, NJ 07921, USA
 Made in India. Mfg. License No.: G/25/2216

5/2022 xxxxxxxx



UVZ
30 x 16mm

Sap Code

Batch Coding
 (For Reference Only)
 LOT: 1234567890
 EXP.: MMM YYYY

Compare to the active ingredient in Abreva®**

NDC 62332-682-03



Docosanol Cream, 10%

Cold Sore/Fever Blister Treatment
 Non-prescription Medicine to Shorten Healing Time*

Portable Convenient Pump



- Cold Sore Treatment
- For Topical Use Only



NET WT
2 g
(0.07 oz)

Open From Here

DOCOSANOL

docosanol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62332-682
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
DOCOSANOL (UNII: 9G1OE216XY) (DOCOSANOL - UNII:9G1OE216XY)		DOCOSANOL	100 mg in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
BENZYL ALCOHOL (UNII: LKG8494WBH)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SUCROSE DISTEARATE (UNII: 33X4X4B90S)				
SUCROSE STEARATE (UNII: 274KW0050M)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62332-682-01	1 in 1 PACKAGE	05/03/2022	
1		2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:62332-682-03	1 in 1 PACKAGE	05/03/2022	
2		2 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA215839	05/03/2022		

Labeler - Alembic Pharmaceuticals Inc. (079288842)

Registrant - Alembic Pharmaceuticals Limited (871411532)

Establishment

Name	Address	ID/FEI	Business Operations
Alembic Pharmaceuticals Limited		871411532	MANUFACTURE(62332-682) , ANALYSIS(62332-682)